

## **RESPONSE TO FINDING IR-00-003-01-FIN**

### **Summary of Finding**

*During performance of an inspection of the Personnel Training and Qualification program conducted March 6-10, 2000 at the Contractor's offices, the Regulatory Unit (RU) identified the following:*

*Section 3.2 of the Contractor's Quality Assurance Program and Implementation Plan (QAPIP), Revision 4, dated May 1998, required "Early identification of potential problems through structured surveillance and audits."*

*Contrary to the above, during the week of March 6-10, 2000, the inspectors found that a quality assurance surveillance (SV-W375-00-QA00003) was performed in October 1999; however, the report and an associated deficiency report (DR-375-99-QA00115) were not issued until February 18, 2000. Furthermore, the required Corrective Action Report (CAR-W375-00-QA00002) was not issued until March 8, 2000. Therefore, the potential problems from the surveillance were not identified to promote improvement to those responsible for potential corrective actions for several months.*

*This is considered an inspection Finding.*

### **Project response:**

#### **1. Agreement or disagreement with the Finding**

The Project agrees with the Finding.

#### **2. Reason for the Finding**

The primary reason for the Finding was insufficient resource allocation to Project Quality Assurance (QA) audit/surveillance activities. Numerous priority tasks required the attention of QA audit/assessment personnel for the period from Mid-October 1999 through February 2000. The highest priority was providing support to an ongoing external assessment, conducted by the U.S. Department of Energy's Office of Civilian Radioactive Waste Management (RW), of the Project's conformance with RW's quality requirements. The breadth and depth of the external assessment had potential for immediate and Project-wide impact.

Typical support activities undertaken during the course of the external assessment included, but were not limited to, responding to eight RW Deficiency Corrective Action Requests (DCARs), providing supporting information for the DCARs, developing root-cause analysis information, formulating an effective corrective action plan, obtaining project-wide approval of the proposed

corrective action plan, and obtaining project management's approval for the entire scope of the follow-on response.

During normal Quality Assurance organization daily activities, responsibility for completion of the formal documentation of the October 1999 surveillance of personnel selection records and issuance of any required deficiency reports and corrective action requests would have been the responsibility of QA audit and assessment personnel. The two QA audit/assessment personnel on staff at the time of this event were part of the total QA resources that provided priority attention to this RW activity. Consequently, as a result of the priority given to those activities, completion of the formal documentation of the October 1999 surveillance of personnel selection records was postponed.

A secondary reason for the Finding is that QA surveillance and corrective action procedures do not provide specific measurable timeframes for completing key elements in the surveillance and corrective action processes. The surveillance procedure does provide direction on how to plan and conduct a surveillance, but lacks specific direction on management expectations for timeframes for reporting and issuing surveillance results. The corrective action procedure contains similar inadequacies. This situation allowed management discretion for the completion of the surveillance without compromising any procedural requirement.

### **3. Corrective steps that have been taken and the results achieved**

The following corrective steps have been taken or will be taken:

A Deficiency Report (DR-W375-00-QA00017\_0) was initiated by Quality Assurance on March 9, 2000, addressing a concern raised by the RU during the ongoing inspection that delays in completion of formal surveillance activities were causing the Project to not meet the Quality Assurance Program and Implementation Plan requirement regarding "early notification of potential problems." The deficiency report recommended:

- Review and document cause and extent of conditions noted
- Initiate appropriate corrective and preventive measures based on review
- Determine process improvements including, but not limited to, timeliness of reporting

The results achieved from responding to the DR identified that out of 177 QA documents initiated in calendar year 1999, 47 audit and surveillance reports, deficiency reports and corrective action reports were not completed and/or sent to Project Document Control (PDC) for distribution and retention in a timely manner. The review did identify that required corrective actions were in progress, but that formal documentation had not been completed. The cause of this backlog is attributed not only to the available QA personnel being assigned to other work activities, but also to an assessment program approval process that was not able to accommodate the volume of issues identified.

Corrective measures have been initiated based on the findings of this review. A dedicated effort has been made by QA to complete actions necessary to address these reports as well as reduce the backlog of open deficiencies. As of June 15, 2000, all but five of these 47 reports have been

sent to PDC for distribution; the five not sent either are being cancelled or have been cancelled for reasons considered valid by QA.

#### **4. The corrective steps that have been or will be taken to avoid further Findings**

There are three corrective steps that Project management has taken to avoid further Findings. These are: 1) increasing the QA organization staff levels to more effectively perform its scope of work on the project, 2) improve the management assessment and corrective action processes to reduce documentation preparation and processing time, and 3) increase management awareness of the importance of the assessment and corrective action processes and provide senior management direction and expectations to the project. This will be accomplished by the use of improved metrics, more detailed procedures, and more comprehensive training.

- Additional personnel resources have been assigned to the QA organization to address current and anticipated QA work. Since January 1, 2000, eight additional experienced quality assurance staff have been added to the QA organization; two were added to the audits and assessments function, and four of the remaining were certified as lead auditors. Performance by the QA organization at this higher staffing level is expected to effectively support overall QA activities associated with the design phase of the Project. Since this staff increase was implemented, the backlog of open deficiencies has been reduced from 58 to 12.
- Surveillance, audit and assessment procedures are currently undergoing a total rewrite. The procedures involved are:
  - K10P008, Management Assessment
  - K13C051, Quality Assurance Audit and Assessment
  - K13P053, Quality Assurance Surveillance
  - K13P062, Quality Trending
  - K13P054, Corrective Action
- The key new elements being incorporated into these procedures are measurable timeframes for completion of Project assessment activities, and identification and completion of corrective actions that address deficiencies and weaknesses. Personnel performing assessment activities will be required to submit the completed assessment report to PDC within 10 working days of approval of the assessment. If a Condition Adverse to Quality is identified during any assessment, the deficiency will automatically be entered into the corrective action process. The corrective action procedure is similarly being revised to identify measurable timeframes for the completion of key elements in the overall corrective action process. For example, the procedure identifies a dwell time of five days for a Condition Adverse to Quality Report to be evaluated and a determination made as to the significance of the item.
- These proposed “timeframe” revisions will be used as management tools in the assessment process to more effectively identify and report performance delinquencies and to initiate immediate and appropriate management actions.

- Metrics (charts) are now used to provide Project management with a summary status of corrective actions. This provides a breakdown of open and overdue corrective actions by department head while showing monthly closure trends. Similar metrics will be established and used to show assessments accomplished, assessments due, and total number of Conditions Adverse to Quality. The use of metrics will ensure continued vigilance in completing and issuing documentation associated with the assessment process.
  - Personnel conducting assessments will be trained on the revised procedures. Specific emphasis will be given on the need for timely communication with the surveilled party during the assessment to ensure management is aware of and can respond to concerns on a “real-time” basis. Timely reporting, database maintenance, and corrective action closure will also be emphasized.
- 5. The date when full compliance with the applicable commitments in the Authorization Basis as it applies to the Finding, i.e., Quality Assurance Program and Implementation Plan, will be achieved.**

The five procedures cited above will be revised to address measurable timeframe elements for completion of key activities by July 28, 2000.

Training on the revised procedures will be provided to Project personnel involved with assessment activities. By August 16, 2000, training on assessment processes, with special emphasis on expected timeframes for completion of the assessment process steps will be provided to appropriate QA personnel, line managers, Environment, Safety, and Health personnel, and personnel in other departments who conduct management assessments.